IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHILIP MORRIS INCORPORATED,
120 Park Avenue
New York, New York,

and

R.J. REYNOLDS TOBACCO COMPANY
401 Main Street
Winston-Salem, North Carolina,

Plaintiffs,

vs.

Civil Action No. _____

UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

and

CAROL BROWNER
Administrator, Environmental
Protection Agency
401 M. Street, S.W.
Washington, D.C. 20460,

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs Philip Morris Incorporated and R.J. Reynolds Tobacco Company, by and through their attorneys, allege as follows:

1. This is an action against defendant Environmental Protection Agency ("EPA" or "Agency") and defendant Administrator Carol Browner seeking review of EPA's classification of environmenal tobacco smoke ("ETS") as a "Group A carcinogen." Plaintiffs also seek

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review of EPA's decision to conduct the risk assessment on which that classification is based, as well as the manner in which that risk assessment was carried out. EPA's actions violate the Administrative Procedure Act ("APA"), and the Radon Gas and Indoor Air Quality Research Act of 1986 ("Radon Act"). Plaintiffs seek a declaration that EPA's ETS Risk Assessment and the resulting EPA designation of ETS as a Group A carcinogen is unlawful, arbitrary and capricious and that the EPA ETS Risk Assessment was conducted unlawfully, arbitrarily, capriciously, and in violation of procedures required by law. Finally, plaintiffs seek a permanent injunction requiring EPA to withdraw its classification of ETS and its ETS Risk Assessment.

2. EPA is charged with preserving the environment and protecting human health within the limits of its statutory authority. Because EPA's decisions are often controversial and affect broad sectors of society and the economy, it is uniformly recognized -- even by the EPA -- that EPA policy and decisionmaking must be based on the highest quality, most objective science possible. Recently, however, the quality and integrity of EPA science has come increasingly under attack. For example, in March 1992, an independent Expert Panel on the Role of Science at EPA -- convened by then-EPA Administrator William Reilly

in 1991 -- issued a report concluding that there were serious problems with the use of science by EPA. The Panel found that EPA science "lacks credible quality assurance, quality control, or peer review" and "does not give sufficient attention to validating the models, scientific assumptions, and databases it uses." The Panel also found that the EPA often ignores science entirely in early decisionmaking and is perceived as "adjusting" science to fit policy. Safeguarding the Future: Credible Science, Credible Decision, The Report of the Expert Panel on the Role of Science at EPA (March 1992).

3. These criticisms are nowhere more justified than in the context of ETS. For at least the last five years, the EPA has pursued a policy of advocating the restriction and ultimate prohibition of smoking on the ground that ETS is a human carcinogen -- despite the lack of a sound scientific basis for this designation. These efforts culminated on January 7, 1993, with the release of EPA's risk assessment of ETS, entitled "Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders" ("ETS Risk Assessment").

4. The ETS Risk Assessment designates ETS as a Group A (human) carcinogen, the most severe carcinoganic designation of substances under EPA's Carcinogen Assessment Guidelines. The Assessment was intended to

and in fact did result in increased restrictions on smoking by private employers and companies and by all levels of government.

5. The ETS Risk Assessment is fundamentally flawed. As alleged below, the EPA was able to reach its desired conclusions only by manipulating data, ignoring critical epidemiological studies, lowering confidence intervals, misinterpreting animal research and in vitro studies, ignoring published chemical analyses, and altering its models, assumptions, and methodologies when use of its usual and typical models, assumptions, and methodologies would not support its predetermined conclusions. Indeed, when EPA's own analysis is subjected to the standard 95% confidence interval used in epidemiological studies, the data do not indicate any statistically significant increase in lung cancer risk from ETS.

6. The ETS Risk Assessment is beyond the EPA's statutory authority, was conducted in a manner that violated the Radon Act, and failed to comply with EPA's specific policies and guidelines with respect to how risk assessments should be performed. It was only by violating both its enabling statute and it's guidelines that EPA was able to release a report that was so contrary to accepted scientific standards and methodologies. The ETS Risk Assessment is arbitrary and

capricious; it evidences EPA's bias in its decisionmaking; and it denies plaintiffs due process of law.

THE PARTIES

7. Plaintiff Philip Morris Incorporated is a subsidiary of Philip Morris Companies with its principal place of business in New York, New York.

8. Plaintiff R.J. Reynolds Tobacco Company [add in].

9. At all times relevant to this action, plaintiffs were and continue to be engaged in the manufacture and distribution of cigarettes and other consumer products. Plaintiffs have been and will continue to be directly affected and injured by defendants' unauthorized and unlawful release of the ETS Risk Assessment.

10. Defendant EPA is an independent agency of the Executive Branch established by Congress, pursuant to the Reorganization Plan of 1970, to coordinate and implement federal governmental action to assure the protection of the environment in accordance with specific statutory authority. As such, EPA is subject to the Radon Act and the APA.

11. Defendant Carol Browner is the appointed Administrator of EPA. This action is maintained against

her only in her official capacity. Administrator Browner ("the Administrator") is responsible either directly or through her subordinates for ensuring that the EPA complies with the terms of the Radon Act and the APA.

JURISDICTION AND VENUE

12. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331. Declaratory relief is authorized by 28 U.S.C. §§ 2201-02 and Fed. R. Civ. P. 57. Judicial review is authorized by 5 U.S.C. §§ 701, et seq.

13. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (e).

FACTUAL ALLEGATIONS

A. The EPA and Its Statutory Authority

14. The sole source of EPA's authority over ETS is the Radon Act. That Act does not refer explicitly to ETS, but grants EPA authority over ETS to the extent ETS is considered an "indoor air pollutant." Except as provided for in the Radon Act, the EPA has no authority over ETS, including ETS in the workplace.

15. The Radon Act was passed in response to an increasing concern that radon gas posed a serious health threat. At no time did Congress consider the extent to

which the Radon Act would grant authority to the EPA over ETS. This is clear in the congressional findings set forth in section 401 of the Radon Act:

> The Congress finds that:
>
> (1) High levels of radon gas pose a serious health threat in structures in certain areas of the country.
>
> (2) Various scientific studies have suggested that exposure to radon, including exposure to naturally occurring radon and indoor air pollutants, poses a public health risk.
>
> (3) Existing Federal radon and indoor air pollutant research programs are fragmented and underfunded.
>
> (4) An adequate information base concerning exposure to radon and indoor air pollutants should be developed by the appropriate Federal agencies.

16. The Radon Act provides the EPA with limited authority over indoor air and its constituents, including ETS. The Radon Act allows the EPA only to establish a research program relating to indoor air quality. The Radon Act does not authorize the EPA either (i) to regulate indoor air quality, or (ii) to conduct any health risk assessments as to radon or any indoor air pollutants. Section 404 of the Act states: "Nothing in this title shall be construed to authorize the Administrator to carry out any regulatory program or any activity other than research, development, and related reporting, information dissemination, and coordination activities specified in this title."

17. Because the Radon Act provides the EPA with no authority to conduct risk assessments, Congress passed another statute, the Radon Assessment and Mitigation Act of 1986, to authorize the EPA to conduct a health risk assessment of radon. Congress has passed no statute authorizing the EPA to conduct any risk assessment of ETS.

18. In addition to restricting the EPA's authority over indoor air to research, Congress required the EPA to follow certain specific procedures in establishing and conducting its research program. Congress required the EPA to submit a plan for implementation of the research program to Congress. Congress also required the EPA at the same time to submit the plan to its Science Advisory Board ("SAB"). After studying it, the SAB was to submit its comments on the plan to Congress. The role of the SAB under the Radon Act is limited to reviewing the research plan and providing comments to Congress.

19. The Radon Act also required the EPA to establish two new committees to assist it in carrying out the research program. The first committee, the "Federal Agency Advisory Committee," was to be composed of representatives from various federal agencies concerned with indoor air. The second committee, the "Radon Act Advisory Committee," was to be composed of

representatives from the States, the scientific community, industry, and public interest organizations.

B. EPA Action Relating to ETS

20. The EPA initiated action against ETS in June 1987, with the release of the Preliminary Indoor Air Pollution Assessment. In June 1988, EPA began a project of drafting policy guidelines relating to ETS in the workplace ("Environmental Tobacco Smoke: A Guide To Workplace Smoking Policies"). The purpose of the project was "to provide information to policy makers on the technical and policy options for instituting workplace smoking policies." In so doing, the EPA acted outside its statutory authority limiting its authority over indoor air to research.

21. Further, at the time the EPA authorized the drafting of workplace policy guidelines, it had conducted no review of the scientific data on the health effects of ETS. Rather, the EPA authorized the creation of policy guidelines based on the assumption that ETS was a human carcinogen. Thus, the EPA initiated the creation of a policy aimed at restricting smoking before it had even reviewed the scientific data to determine whether the hazard upon which the policy was to be based even existed.

22. The EPA also placed policy ahead of science by choosing to retain the Smoking Policy Institute

("SPI") to prepare the workplace smoking policy guidelines. The EPA knew that SPI had a strong financial interest in declaring ETS a carcinogen: SPI was in the business of assisting employers to ban or restrict smoking in the workplace. For this reason alone, it is no surprise that the draft document ultimately prepared by the SPI met the EPA's policy objective of advocating the restriction of smoking in the workplace.

23. In 1989, the EPA initiated the ETS Risk Assessment project. The purported purpose of this project was to evaluate the existing research on the health effects of ETS and classify ETS according to the EPA's carcinogen assessment guidelines. The latter task -- the classification of ETS -- had no legitimate research purpose and could serve only a regulatory purpose, which was beyond the scope of the EPA's authority under the Radon Act.

24. To prepare the initial draft of the ETS Risk Assessment, the EPA hired an outside consultant, Kenneth Brown. Mr. Brown prepared the draft without any consultation with either the Federal Agency Advisory Committee or the Radon Act Advisory Committee, as required by the Radon Act.

25. By 1990, Mr. Brown had prepared the initial draft document, which advocated classification of ETS as

a Group A ("known human") carcinogen. In May 1990, the ETS Draft Risk Assessment was leaked to the media, which widely publicized it for more than a month before the EPA made copies available to the plaintiffs and the public in general. Finally, on June 25, 1990, the EPA formally released its review draft, "Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children" (hereinafter "ETS 1990 Draft Risk Assessment"). At the same time, the EPA released its draft workplace smoking policy guidelines, "Environmental Tobacco Smoke: A Guide to Workplace Smoking Policies."

26. By releasing these two documents together, the EPA impermissibly combined the separate functions of risk assessment and risk management. At the time when the EPA's risk assessment was in the initial stages of public review, the EPA's Workplace Smoking Policy Guide had already assumed carcinogenicity and was providing policy guidelines for "implementing" smoking restrictions and "strategies" to reduce exposure to smoking.

27. The EPA subsequently referred the ETS 1990 Draft Risk Assessment and a portion of the Workplace Smoking Policy Guide to the Indoor Air Quality and Total Human Exposure Committee (IAQTHEC) of the SAB. The EPA violated the Radon Act by failing to refer the draft

assessment to the Federal Agency Advisory Committee, the Radon Gas Act Advisory Committee, or the entire SAB as specifically required by the Act. The IAQTHEC is not now nor ever has been composed of individuals representing the States, federal agencies, industry or public interest organizations.

28. As a result of this violation of the Radon Act, representatives from the States, industry, and public interest organizations were effectively and unlawfully precluded from participating in the evaluation of the EPA Risk Assessment in the manner specifically required by Congress.

29. The IAQTHEC reviewed the EPA's Draft Risk Assessment and held a meeting on December 4-5, 1990 in Washington, D.C. The IAQTHEC subsequently reviewed a revised ETS Draft Risk Assessment at a public meeting in Washington, D.C. on July 21-22, 1992. In its report to the executive committee of the SAB, IAQTHEC acknowledged that a draft of the ETS Risk Assessment did not adhere to Agency guidelines for classification of carcinogens, but dismissed such concerns with the suggestion that the guidelines simply be changed.

30. On January 7, 1993, EPA released its final ETS Risk Assessment. The ETS Risk Assessment designates ETS as a Group A (human) carcinogen and projects a mortality rate for ETS exposure of approximately 3000

lung cancer deaths each year in the United States. EPA's projected mortality rate and classification of ETS as a Group A carcinogen were intended to and had the effect of placing restrictions on the smoking of cigarettes and is therefore agency action in direct violation of the Radon Act.

C. The Nature of Agency Action And the Plaintiffs' Harm

31. The ETS Risk Assessment, which reached the regulatory conclusion that ETS is a Group A carcinogen, constitutes "agency action" as defined in section 551(13) of the APA. Moreover, the ETS Risk Assessment constitutes "final agency action" within the meaning of section 704 of the APA because:

a. The EPA released the ETS Risk Assessment to the public as a final and unequivocal agency conclusion and decision;

b. The ETS Risk Assessment was formally released by the EPA administrator; and

c. The EPA is contemplating no further action regarding work on the ETS Risk Assessment.

32. As a direct and proximate result of the release of the ETS Risk Assessment, plaintiffs have been severely injured. The assessment was intended to and in fact did result in the imposition of greater

restrictions on the smoking of cigarettes in public and in the workplace.

33. Specifically, as a result of the ETS Risk Assessment and classification of ETS as a Group A carcinogen, private entities and governments throughout the country have already undertaken action or are actively considering taking action to restrict smoking, as evidenced below:

a. Numerous large private employers, including Dow Chemical Co., Southern California Edison Co., Ratheon Corp., Belz enterprises, Hewitt Assoc., and Foster Higgins & Co., have expanded workplace smoking restrictions or instituted total workplace smoking bans.

b. Restaurants have initiated smoking bans. For example, McDonald's Corporation has initiated a test smoking ban in approximately 40 of its restaurants. McDonald's could expand the ban to include all 9000 restaurants in its nationwide fast-food chain.

c. At least one insurance company is offering discounts on group term life insurance rates for new policyholders who have a 100% smoke-free workplace.

d. The Board of Directors of the Building Owners and Managers Association International, representing more than 5 billion square feet of North American office space, passed a resolution supporting a federal ban on smoking in the workplace.

e. The Governors of Kentucky and California have already issued executive orders that make those states' public smoking laws more restrictive. Other states including Colorado, Delaware, Hawaii, Illinois, Iowa, Kansas, Maryland, Missouri, Minnesota, Montana, Nebraska, New York, Ohio, Texas, Utah, Vermont, and Virginia have proposed legislation to ban or restrict smoking in workplaces and other public areas.

f. The U.S. Secretary of Labor has directed the Administrator of the Occupational Safety and Health Administration (OSHA) "to commence a rulemaking to address the hazards of occupational exposure to secondhand smoke."

g. Legislation was introduced in Congress which would prohibit smoking (i) in all federally funded indoor facilities that serve children under age 18, "Preventing Our Kids From Inhaling Deadly Smoke (PRO-KIDS) Act of

1993," and (ii) in all structures owned or leased for use by a Federal agency, including the executive and judicial branch, "Preventing Our Federal Building Workers and Visitors Exposure to Deadly Smoke (PRO-FEDS) Act of 1993."

Plaintiffs' pervasive, ongoing harm is the result of the EPA's unlawful conduct, which has occurred and will continue to occur unless this Court grants the relief plaintiffs seek in this complaint.

D. The ETS Risk Assessment Is Arbitrary and Capricious

34. The EPA conducted the ETS Risk Assessment with the predetermined conclusion that ETS is a human carcinogen. The EPA reached this conclusion solely for policy reasons -- to justify smoking restrictions in the workplace and discourage smoking in general. To reach its conclusion, the EPA manipulated scientific data, ignored contrary studies, and employed scientific models, assumptions, and methodologies never used before and not accepted by the scientific community. Simply stated, the ETS Risk Assessment has no scientific foundation -- it is arbitrary and capricious.

35. In particular, the EPA bases its risk assessment on (a) epidemiologic studies and (b) the

purported similarities between mainstream smoke and ETS. Neither supports the EPA's conclusion.

1. Epidemiology

36. The EPA's use of epidemiology to support its Group A carcinogen designation was fundamentally flawed for at least three reasons. First, the great majority of the epidemiological studies relied on by the EPA do not show -- and never purported to show -- a statistically significant association between ETS and lung cancer. Second, the EPA refused to consider data (including two entire studies) which did not support the EPA's conclusions. Third, the EPA was able to produce a statistical association only by "reanalyzing" data presented in the studies in a manner inconsistent with prevailing scientific standards and methodologies. For example, the EPA intentionally lowered the confidence interval from 95% to 90% to obtain an apparent association and failed to control for known confounding risk factors.

(a) Lack of Reported Association

37. The EPA relied on 11 U.S. epidemiologic studies for its classification of ETS as a carcinogen. None of those studies reported an overall risk estimate for lung cancer that was statistically significant. Indeed, as alleged below, even when the EPA lowered the statistical confidence limits for the U.S. studies from

the standard 95% to 90%, all but one of the 11 studies still did not achieve statistical significance.

38. The EPA also analyzed 19 other epidemiologic studies from seven countries other than the United States. Of these 19 studies, 13 reported no statistically significant overall association between ETS and lung cancer. Put another way, of the 30 studies reviewed by the EPA in all, 24 -- a full 80% -- did not support the Agency's findings.

39. The six studies that found a statistically significant association were all conducted outside the United States. The studies used inconsistent methods and reached inconsistent results. The EPA failed to investigate whether the statistically significant associations reported in those studies were due to ETS or were the result of confounding caused by the existence of some other risk factors.

40. In relying on the 30 studies, the EPA selectively chose what data to use. Specifically, the EPA limited its examination to the reported associations between spousal smoking status and lung cancer. Although 12 of the 30 studies also considered workplace exposure to ETS, the ETS Risk Assessment ignored the workplace data. Similarly, although 11 of the 30 studies contained reports regarding home exposure to ETS during childhood, the ETS Risk Assessment ignored that

data. The refusal of the EPA to consider these data was scientifically unjustified, bias, arbitrary, and capricious.

41. If the EPA had not ignored the data on workplace exposure and childhood residential exposure, the Agency would have found additional evidence against its conclusions.

a. Ten of the 12 studies examining workplace exposure found no statistically significant association with lung cancer. The two that did involve special circumstances. One of the studies (Fontham 1991) is incomplete and hence the weak association reported in that study cannot be evaluated. The second study (Kabat & Wynder 1984) reported a barely statistically significant association between workplace exposure and lung cancer in males and no statistically significant association between workplace exposure and lung cancer in females. Kabat and Wynder stated in their paper that the data on male subjects should be interpreted with caution.

b. If the data on workplace exposure reported in the 12 studies are pooled in a meta-analysis such as the one conducted in the ETS Risk Assessment, the data would

yield no association between reported workplace exposures to ETS and lung cancer in nonsmokers.

c. Similarly, ten of the 11 studies examining home exposure during childhood reported no statistically significant association for lung cancer in adult nonsmokers. The single exception employed a process called "data dredging," a method not accepted by the scientific community.

(b) Ignored Studies

42. The EPA also ignored major studies on ETS without explanation. Prior to the release of the ETS Risk Assessment on January 7, 1993, two additional studies appeared examining the association between spousal smoking status and lung cancer (Brownson, et al., 1992, and Stockwell, et al., 1992). The Brownson study is an especially critical study. Funded in part by the National Cancer Institute, the Brownson study is one of the largest studies ever conducted on ETS exposure and lung cancer incidence.

43. The EPA had access to both studies well in advance of the release of the final ETS Risk Assessment. If the EPA had included the Brownson and Stockwell studies in their meta-analysis, the Agency would have

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found no statistically significant increase in lung cancer risk.

44. A meta-analysis including the Brownson and Stockwell studies was forwarded to the EPA more than one month prior to the release of the final ETS Risk Assessment. The EPA chose not to modify its statistical calculations in the final ETS Risk Assessment. The EPA's failure to include these two studies in its ETS Risk Assessment was arbitrary and capricious.

(c) Other Methodological Flaws

45. Finally, the EPA's epidemiology has other fundamental methodological flaws. To obtain the results it wanted, the EPA combined the 11 individual U.S. studies using a statistical technique known as meta-analysis. The EPA's meta-analysis was scientifically unsound, arbitrary and capricious for at least five reasons.

46. First, in order to achieve a statistically significant association in its final report, the EPA lowered the confidence interval from 95% to 90%. A confidence interval measures the probability that a statistical association was obtained by chance. The EPA's lowering of the confidence interval doubled the probability that the association was due to chance. The EPA's use of a lower confidence interval cannot be justified scientifically in light of the following:

a. The EPA and other Federal agencies have consistently used a 95% confidence interval in all other risk assessments that have relied upon epidemiological studies;

b. Virtually all of the ETS studies upon which the EPA relied used a 95% confidence interval;

c. The 1990 Draft Risk Assessment used a 95% confidence interval;

d. Lowering the confidence interval was the only way the EPA could reach its conclusion of increased risk for the U.S. population; and

e. The ETS Risk Assessment does not discuss the effect that lowering the confidence interval had on the data.

47. The effect of the EPA's manipulation of the data is revealed when the standard 95% confidence interval is used. A meta-analysis of the U.S. studies employing all of EPA's (flawed) methodologies and assumptions but using a 95% confidence interval yields no statistically significant result. And when the Brownson and Stockwell studies are added, the results are not statistically significant even at a 90% confidence interval.

48. Second, the EPA ignores the high likelihood that confounding factors might be responsible for the reported association between spousal smoking status and lung cancer. The scientific literature identifies the following factors as potential confounders: diet, personal medical history, family health history, lifestyle choices, occupational factors, and environmental factors. Yet, the ETS Risk Assessment does not even acknowledge the existence of confounders.

49. Further, the EPA was able to obtain a risk estimate for ETS of only 1.19, when a risk estimate of 1.0 shows no association at all. Epidemiologists agree that any relative risk of less than 2.0 is weak. The EPA ignores this fact and the fact that the relative risks for some of the confounding factors exceed 2.0 and are large enough to account completely for the reported association between spousal smoking status and lung cancer.

50. Third, the ETS Risk Assessment ignores various sources of bias in the spousal smoking studies. These include publication bias, recall bias among cases, disease misclassification, and diagnostic misclassification. The EPA identifies only one bias -- smoking status misclassification -- and adjusts for it by employing a scientific model that had been neither subjected to peer review nor published. The model

contains numerous mathematical and conceptual errors, including a misclassification rate that is not representative of the U.S. population. If a realistic misclassification rate were used, EPA's meta-analysis would yield no significant association between spousal smoking status and lung cancer.

51. Fourth, the ETS Risk Assessment is not based on accurate or verifiable information concerning individual exposure to ETS. The EPA relied upon questionnaires whose accuracy depends on the individual's ability to recall past events, such as how much a husband smoked in the past 20 to 30 years. People's recollection about such events over such a long period of time is inherently unreliable, and no attempt was made to verify the information obtained.

52. Finally, the EPA's meta-analysis violated the most fundamental principle of meta-analysis -- it did not aggregate similar data. For example, some of the studies attempted to account for bias and the existence of confounding risk factors; others did not. In conducting the meta-analysis, the EPA combined data irrespective of whether the data were raw, "adjusted," or presented in summary form -- none of which are comparable.

53. As alleged above, notwithstanding all of its manipulations and methodological flaws, the EPA was able

to calculate a risk estimate for ETS of no higher than 1.19 -- under any test, an extremely weak indication of risk. Nonetheless, the EPA decided to place ETS in the highest category of carcinogens established in the Carcinogen Assessment Guidelines: a Group A (known human) carcinogen.

2 "Biological Plausibility"

54. The EPA excuses the weaknesses of the epidemiologic data on which it relied by claiming "biological plausibility" -- that active smoking and exposure to ETS are the same. But, as with its meta-analysis, the ETS Risk Assessment's comparisons of ETS and mainstream smoke (the smoke inhaled by the smoker) are based on a selective review of the literature, coupled with a series of unfounded -- and demonstrably false -- assumptions. Indeed, previous scientific reviews of ETS -- including reviews by the U.S. Surgeon General and the National Academy of Sciences -- have cautioned against such comparisons, stressing that there are significant differences between ETS and mainstream smoke that make any such comparison scientifically unjustified.

55. ETS is a highly diluted, aged, and chemically altered mixture of sidestream smoke (the smoke emitted from the burning end of the cigarette) and exhaled mainstream smoke. The chemical composition of

this mixture changes as it ages and interacts with other materials present in a room. The tobacco smoke to which the nonsmoker is exposed is both physically and quantitatively different from mainstream smoke.

56. The ETS Risk Assessment totally ignores these differences and does not attempt any chemical comparison of ETS and mainstream smoke. For example, it does not attempt to ascertain which components of mainstream smoke are allegedly responsible for claimed adverse health effects and whether those components are present in ETS (and, if so, at what levels).

57. The animal evidence discussed in the ETS Risk Assessment also provides no support for the proposition that mainstream smoke and ETS are similar. There are no reported mouse skin painting studies of ETS condensate. There also are no implantation studies of ETS condensate, and in vitro genotoxic studies provide neither direct nor sufficient evidence of carcinogenicity.

58. Instead, the EPA cites studies that have used undiluted sidestream smoke condensate collected under conditions that could easily have modified the condensate. For these purposes, the EPA Risk Assessment assumes that sidestream smoke is identical to ETS. This assumption is no more justified than is the assumption that ETS is identical to mainstream smoke.

59. In short, in light of the available scientific literature, the ETS Risk Assessment's comparison of ETS and mainstream smoke cannot justify either reliance on the extremely weak ETS epidemiology or the application of active smoking epidemiology to ETS. The ETS Risk Assessment's approach does not even begin to satisfy the basic principles of hazard identification in conducting risk assessments.

60. Finally, even if there were a legitimate basis for comparing active smoking to ETS, the comparison would not support a finding of significant risk from exposure to ETS. Epidemiologic studies indicate that active smoking of fewer than four cigarettes per day is not associated with a significant increased incidence of lung cancer. Four cigarettes per day far exceeds the highest dose attributable to ETS. Published exposure estimates indicate that a nonsmoker exposed to ETS under everyday conditions would have to spend from 100 to 1000 hours in an office, restaurant, or public place where smoking is occurring in order to be exposed to the equivalent of even a single cigarette.

E. The EPA's Failure to Follow Its Own Guidelines

61. The EPA was only able to release the ETS Risk Assessment by (1) violating the Radon Act which limits the EPA's authority over ETS research, (2)

failing to comply with the congressional directive that EPA conduct its research with the assistance of advisory committees reflecting various points of view including that of industry and, (3) ignoring its own policies and guidelines. The EPA's violations of congressional requirements are alleged supra at paragraphs ___ - ___.

62. In conducting its ETS Risk Assessment, the EPA failed to comply with the following agency guidelines: (a) "Guidelines for Carcinogen Risk Assessment," 51 Fed. Reg. 33,92 (Sept. 24, 1986) ("Carcinogen Assessment Guidelines") and (b) "Guidelines for Exposure Assessment," 57 Fed. Reg. 22,88 (May 29, 1992) ("Exposure Assessment Guidelines"). In addition, the EPA violated its policies as set out in Credible Science, Credible Decisions, The Report of the Expert Panel on the Role of Science at EPA (March 1992) ("Safeguarding the Future").

1. Carcinogen Assessment Guidelines

63. In 1986, the EPA issued the Carcinogen Assessment Guidelines to ensure that the agency follows uniform scientific standards and procedures in evaluating suspected carcinogens. Compliance with the guidelines is mandatory, and members of the general public, including plaintiffs, have a legitimate expectation that the guidelines will be followed:

> The purpose of these Guidelines is to promote quality and consistency of carcinogen risk assessment within the EPA and to inform those outside the EPA about its approach to carcinogen risk assessment. These Guidelines emphasize the broad but essential aspects of risk assessment that are needed by experts in the various disciplines required (e.g., toxicology, pathology, pharmacology, and statistics) for carcinogen risk assessment.

51 Fed. Reg. at 33,93. (Emphasis added.)

64. The purpose of these guidelines is to prevent exactly what occurred in this case: performance of a risk assessment based on policy, not science. The ETS Risk Assessment violated the Carcinogen Assessment Guidelines in at least eight respects.

65. First, the Carcinogen Assessment Guidelines require that inferences of causation based on epidemiology meet three criteria:

> 1. There is no identified bias that could explain the association.
>
> 2. The possibility of confounding has been considered and ruled out as explaining the association.
>
> 3. The association is unlikely to be due to chance.

51 Fed. Reg. at 33,99. (Emphasis added.) The ETS Risk Assessment complies with none of these criteria. As noted above, the EPA ignored numerous sources of bias, failed to account for confounding factors identified in the scientific literature, and violated widely accepted

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principles of statistical analysis designed to minimize the possibility that an association is due to chance.

66. Second, because ETS is designated as a Group A carcinogen, the Carcinogen Assessment Guidelines require the EPA to ensure that "[s]tudies are evaluated according to sound biological and statistical considerations and procedures." 51 Fed. Reg. at 33,94. However, as set forth above, to obtain a conclusion of increased risk, the EPA used unsound statistical considerations and procedures in lowering the confidence intervals in the epidemiologic studies from 95% to 90% and in performing a meta-analysis of dissimilar, already aggregated data. Moreover, the EPA engaged in unjustified biological assumptions in applying the studies on mainstream smoke to ETS.

67. Third, because ETS is designated as a Group A carcinogen, the Carcinogen Assessment Guidelines require that the EPA's evidence from epidemiologic studies be "sufficient." 51 Fed. Reg. at 34,000. The opposite is clearly true. As noted above, none of the epidemiological studies conducted in the United States reviewed by the EPA reported a statistically significant association, and a full 80% of all studies reported no statistically significant risk. The existing scientific evidence is simply not "sufficient" to support the EPA's conclusions.

68. Fourth, because the Risk Assessment purports to assess ETS quantitatively by estimating lung cancer deaths from ETS exposure, the Carcinogen Assessment Guidelines require the assessment to contain a section "in which the results of [a] dose-response assessment must be combined with an estimate of the exposures to which the populations of interest are likely to be subject." 51 Fed. Reg. at 33,998. As alleged above, EPA's dose-response and exposure assessments ignore the existing literature and are manifestly inadequate. Those assessments were then combined into a risk characterization that also is scientifically unsound.

69. Fifth, the Carcinogen Assessment Guidelines require the EPA to give full consideration to "all relevant scientific information." 51 Fed. Reg. at 33,992. Yet, the EPA refused to consider two published epidemiologic studies on spousal smoking status and lung cancer, one of which is among the largest ever conducted. The EPA also failed to consider (i) the workplace exposure data reported in 12 of the 30 studies examined in the risk assessment, (ii) the data on home exposure during childhood reported in 11 of the 30 studies, (iii) the data from well over 35 published studies which monitored ETS constituents in indoor air, (iv) data regarding the physical and chemical characterization of ETS, (v) results from published

animal studies and in vitro studies, and (vi) data on identified sources of bias and confounding factors.

70. Sixth, the Carcinogen Assessment Guidelines require the EPA to "fully present" all relevant scientific information in the ETS Risk Assessment document. 51 Fed. Reg. at 33,992. The ETS Risk Assessment fails to "fully present" the critical scientific information alleged above.

71. Seventh, the Carcinogen Assessment Guidelines require the EPA to "use the most scientifically appropriate interpretation to assess risk." 51 Fed. Reg. at 33,992. Again, the EPA did the opposite. As alleged above, the EPA improperly lowered the confidence intervals, combined dissimilar data into a meta-analysis, and applied the data on mainstream smoke to ETS.

72. Eighth, the Carcinogen Assessment Guidelines require agency scientists to "identify the strengths and weaknesses of [the ETS Risk Assessment] by describing uncertainties, assumptions and limitations, as well as the scientific basis and rationale" for the assessment. 51 Fed. Reg. at 33,992. The EPA failed to even mention -- let alone describe -- the numerous uncertainties, assumptions and limitations alleged in the foregoing paragraphs, despite having received detailed, written

comments relating to all of them well in advance of the release of the ETS Risk Assessment.

73. Given the inadequacy of the ETS epidemiology, the critical differences between ETS and mainstream smoke, and the lack of supportive animal data, the Carcinogen Assessment Guidelines prohibit the classification of ETS as a Group A carcinogen. Indeed, no other substance has been classified as a Group A carcinogen based on (i) a clear majority of epidemiologic studies finding no statistically significant association or (ii) extrapolation of data from one substance to another. Moreover, no other substance has been classified as a Group A carcinogen when there has been such a complete absence of corroborating animal data.

2. Exposure Assessment Guidelines

74. In 1992, the EPA issued its Exposure Assessment Guidelines which also govern EPA risk assessments. Like the Carcinogen Assessment Guidelines, the purposes of the Exposure Assessment Guidelines are "to promote consistency and technical quality in risk assessment, and to ensure that the risk assessment process is maintained as a scientific effort separate from risk management." 57 Fed. Reg. at 22,888.

75. The ETS Risk Assessment violated the Exposure Assessment Guidelines in at least three respects.

a. First, the Exposure Assessment Guidelines require that "exposure estimates along with supporting information . . . be fully presented in Agency risk assessment documents." 57 Fed. Reg. at 22,888. This was simply not done. For example, the EPA completely failed to include the data from over 35 studies which monitored ETS constituents in indoor air.

b. Second, the guidelines direct the EPA to "identify the strengths and weaknesses of each assessment by describing uncertainties, assumptions, and limitations, as well as the scientific bases and rationale for each assessment." 57 Fed. Reg. at 22,888. As noted above, the EPA made no effort to identify the numerous uncertainties, assumptions and limitations of its risk assessment alleged above. The EPA even failed to mention the critical fact that no actual exposure data exist for <u>any</u> of the epidemiologic studies relied upon by the ETS Risk Assessment. Instead, the epidemiologic studies "manufactured" their own "exposure data" based on flawed assumptions that were never validated.

c. Finally, the Exposure Guidelines require that "[e]xposure information must be clearly linked to the hazard identification and dose-response relationship." 57 Fed. Reg. at 22,905. This also was not done. The EPA failed to include in the ETS Risk Assessment a scientifically valid hazard identification evaluation, which, at a minimum, would have taken into account chemical and animal studies on ETS. Likewise, the EPA failed to include a dose-response evaluation that reviewed the actual data and results reported in the epidemiologic studies.

3. Safeguarding the Future Report

76. As noted in paragraph 1 above, in March 1992 an expert panel convened to study the role of science in the EPA issued a report entitled Safeguarding the Future: Credible Science, Credible Decisions, The Report of the Expert Panel on the Role of Science at EPA, (March 1992). The Safeguarding the Future Report offered the following criticisms and conclusions:

a. "EPA . . . does not give sufficient attention to validating the models, scientific assumptions, and databases it uses;"

b. "EPA has not always ensured that contrasting, reputable scientific views are

well-explored and well-documented from the beginning to the end of the regulatory process;"

c. "EPA science is perceived by many people, both inside and outside the Agency, to be adjusted to fit policy. Such 'adjustments' could be made consciously or unconsciously by the scientist or the decisionmaker;" and

d. "The interpretation and use of science is uneven and haphazard across programs and issues at EPA."

77. The EPA accepted the criticisms of its science set out in the Report. The EPA also made it binding agency policy to implement the Report's recommendations.

78. Virtually all of the Report's criticisms are applicable to the EPA's activities with respect to ETS. As detailed in the paragraphs above, the EPA has violated agency assessment guidelines, manipulated data, ignored studies, breached accepted principles of statistical analysis, and misinterpreted animal and in vitro studies. All this was done for a single purpose: to provide the EPA and others with a "scientific foundation" on which to base a preordained policy of smoking restriction. Indeed, as noted above, the EPA initiated the policymaking process before undertaking its own scientific review of the alleged hazard. (See

Paragraphs __ to __.) In direct violation of agency policy and in Orwellian fashion, the EPA "adjusted" its science to fit its antismoking social agenda.

COUNT I

THE ETS RISK ASSESSMENT AND THE RESULTING ETS CLASSIFICATION WAS CONDUCTED UNLAWFULLY, ARBITRARILY, CAPRICIOUSLY, AND IN VIOLATION OF DUE PROCESS

79. Plaintiffs incorporate herein by reference paragraphs 1 through ___ of the complaint.

80. The ETS Risk Assessment and the resulting ETS classification as a Group A carcinogen are based on incomplete, irrelevant, and inconsistent data.

81. The ETS Risk Assessment ignores available, persuasive scientific data contrary to its conclusions.

82. The ETS Risk Assessment utilizes models, assumptions, and methodologies that are inaccurate, flawed, and not accepted by the scientific community. In conducting and issuing the ETS Risk Assessment, defendants altered EPA's usual and typical procedures and methodologies to support the conclusion that ETS is a Group A carcinogen when use of EPA's usual and typical procedures and methodologies would not support that conclusion.

83. The ETS Risk Assessment is not supported by existing state of scientific or medical knowledge.

84. Defendants' actions in initiating, sponsoring, conducting, issuing, and releasing the ETS Risk Assessment are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," as provided in Section 706(2)(A) of the APA, and violate plaintiffs' due process rights.

85. As a direct and proximate cause of defendants' unlawful acts, plaintiffs have been seriously injured as set forth herein.

WHEREFORE, plaintiffs pray this Court grant the plaintiffs the following relief:

(A) To declare that the ETS Risk Assessment was conducted unlawfully, arbitrarily, capriciously, in violation of precedures required by law, and in violation of due process;

(B) To declare that the resulting EPA designation of ETS as a Group A carcinogen is unlawful, arbitrary and capricious;

(C) To grant an injunction requiring EPA to withdraw its classification of ETS as a Group A carcinogen and to withdraw the ETS Risk Assessment upon which that classification is based; and

(D) To grant plaintiffs such additional relief that the Court may deem just and proper.

COUNT II

EPA ILLEGALLY CONDUCTED THE ETS RESEARCH PROGRAM AND IT LACKED AUTHORITY UNDER THE RADON ACT TO PREPARE AND ISSUE THE RISK ASSESSMENT ON ETS AND TO CLASSIFY ETS, THEREBY VIOLATING PLAINTIFFS' DUE PROCESS RIGHTS

86. Plaintiffs incorporate herein by reference paragraphs 1 through __ of the complaint.

87. An administrative agency has no power to act unless and until Congress confers power upon it. To the extent EPA has any authority over ETS, it derives from the Radon Act.

88. Section 401 of the Radon Act provides EPA with authority restricted to conducting "research, development, and related reporting, information dissemination, and coordination activities." The Radon Act expressly bars the EPA from carrying out "any regulatory programs."

89. Defendants, purporting to rely on the Radon Act, have conducted and issued the ETS Risk Assessment and have classified ETS as a "Group A carcinogen."

90. The ETS Risk Assessment is not research or related activities as narrowly authorized by the statute. Furthermore, EPA's classification of ETS as a Group A carcinogen has no legitimate research purpose, but is designed and intended solely to achieve a regulatory impact and effect. In conducting and

releasing the ETS Risk Assessment and in classifynig ETS as a Group A carcinogen, defendants have gone beyond research on an indoor air constituent and instead have conducted a unique, unauthorized and unlawful health risk assessment.

91. EPA exceeded its statutory authority under Sections 403 and 404 of the Radon Act by conducting and issuing a risk assessment on ETS and by classifying ETS as a Group A carcinogen.

92. Defendants further violated the Radon Act by not properly establishing the Radon Act Advisory Committee mandated by Section 403(c) of the Radon Act. The Radon Act provides that that Committee is to provide EPA with the input from industry and the public required to assist the defendants in carrying out research programs under the Radon Act. Because no such committee was ever formed, the defendants' activities regarding ETS research and related activities also violate the Radon Act and exceed EPA's statutory authority.

93. Under Section 403(c) of the Radon Act, the Administrator was also required to establish a Federal Agency Advisory Committee composed of individuals representing Federal Agencies. Although the EPA Administrator has designated The Committee on Indoor Air Quality (CIAQ) as this Federal Agency Advisory Committee, the CIAQ in fact has not assisted the

Administrator in carrying out the research program. For this additional reason, the defendants' activities regarding ETS research and related activities further violate the Radon Act and exceed EPA's statutory authority.

94. EPA's action in conducting and issuing the ETS Risk Assessment is "in excess of statutory jurisdiction, authority, or limitations or short of statutory right" and, therefore, is in derogation of the public interest as defined by the statute passed by Congress and should be held "unlawful" and "set aside" in accordance with section 706(2) of the APA and in accordance with plaintiffs' due process rights.

95. As a direct and proximate cause of defendants' unlawful acts, plaintiffs have been seriously injured as set forth herein.

WHEREFORE, plaintiffs pray this Court grant the plaintiffs the following relief:

(A) To declare that EPA's performance and issuance of the ETS Risk Assessment and classification of ETS as a Group A carcinogen exceeded its authority prescribed by Sections 403 and 404 of the Radon Act, and thereby was in contravention of Section 706(2)(C) of the APA and violated plaintiffs' due process rights;

(B) To declare that any ETS research programs, including the results thereof, conducted pursuant to the

authority of the Radon Act without the assistance of the Federal Agency Advisory Committee or the assistance of a properly comprised Radon Act Advisory Committee are unlawful because they are in excess of the authority of the defendants; and

(C) To declare the ETS Risk Assessment and classification were conducted unlawfully and in violation of statutory procedures;

(D) To grant an injunction requiring EPA to withdraw its classification of ETS as a Group A carcinogen, to withdraw its ETS Risk Assessment and to withdraw the results of its ETS research program; and

(E) To grant plaintiffs such additional relief that the Court may deem just and proper.

COUNT III

DEFENDANTS HAVE VIOLATED DUE PROCESS AND THE APA BY FAILING TO COMPLY WITH EPA'S OWN POLICY AND GUIDELINES AND WITH OTHER PROCEDURES REQUIRED BY LAW

96. Plaintiffs incorporates herein by reference the allegations contained in paragraphs 1 through _____ of this Complaint.

97. In their activities related to the ETS Risk Assessment, defendants violated the Carcinogen Assessment Guidelines.

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98. In their activities related to the ETS Risk Assessment, defendants violated their Exposure Assessment Guidelines.

99. In their activities related to the ETS Risk Assessment, defendants violated EPA's policies as set forth in the Safeguarding the Future report.

100. Defendants' violations of EPA policies and guidelines as set forth above, individually and collectively, ensured a conclusion (that ETS is a Group A carcinogen) that could not have been reached but for such violations.

101. As a result of defendants' violation of EPA's guidelines and policies, the ETS Risk Assessment was conducted "without observation of procedure required by law" under Section 706(2)(D) of the APA and in violation of due process.

102. As a direct and proximate cause of defendants' unlawful acts, plaintiffs have been seriously injured as set forth herein.

WHEREFORE, plaintiffs pray this Court grant the plaintiffs the following relief:

(A) To declare that defendants conducted the ETS Risk Assessment unlawfully, arbitrarily, capriciously, in violation of procedures required by law" under Section 706(2)(D) of the APA and in violation of due process;

(B) To declare that the ETS Risk Assessment and the resulting EPA designation of ETS as a Group A carcinogen is unlawful, arbitrary and capricious;

(C) To grant an injunction requiring EPA to withdraw its classification of ETS as a Group A carcinogen and to withdraw its ETS Risk Assessment; and

(D) To grant plaintiffs such additional relief that the Court may deem just and proper.